Suliqua

Procedural steps taken and scientific information after the authorisation

Application number	Scope	Opinion/ Notification[1] issued on	Commission Decision Issued[2] / amended on	Product Information affected[3]	Summary
IAIN/0044	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	22/10/2024		SmPC and PL	
WS/2732	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008.	17/10/2024	n/a		

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

	B.I.a.1.j - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Replacement or addition of a site where batch control/testing takes place and any of the test method at the site is a biol/immunol method				
N/0042	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	13/09/2024		PL	
PSUSA/10577 /202311	Periodic Safety Update EU Single assessment - insulin glargine / lixisenatide	27/06/2024	22/08/2024	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10577/202311.
IB/0039/G	This was an application for a group of variations. B.I.c.2.z - Change in the specification parameters and/or limits of the immediate packaging of the AS - Other variation B.I.c.2.z - Change in the specification parameters and/or limits of the immediate packaging of the AS - Other variation	26/02/2024	n/a		
II/0037/G	This was an application for a group of variations. B.II.b.3.b - Change in the manufacturing process of the finished or intermediate product - Substantial changes to a manufacturing process that may have a significant impact on the quality, safety and efficacy of the medicinal product B.II.b.4.d - Change in the batch size (including batch size ranges) of the finished product - The change	15/02/2024	n/a		

	relates to all other pharmaceutical forms manufactured by complex manufacturing processes				
IA/0041/G	This was an application for a group of variations. B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place	01/02/2024	n/a		
WS/2570	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.b.2.e - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure (including replacement or addition) for the AS or a starting material/intermediate	18/01/2024	n/a		
WS/2539	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.a.2.a - Changes in the manufacturing process of the AS - Minor change in the manufacturing process of the AS	07/09/2023	n/a		

N/0035	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	17/07/2023	06/06/2024	PL	
PSUSA/10577 /202211	Periodic Safety Update EU Single assessment - insulin glargine / lixisenatide	08/06/2023	n/a		PRAC Recommendation - maintenance
IB/0033	B.I.a.2.e - Changes in the manufacturing process of the AS - Minor change to the restricted part of an ASMF	16/05/2023	n/a		
WS/2418	This was an application for a variation following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. Update of section 4.8 of the SmPC in order to cholelithiasis and cholecystitis to the list of adverse drug reactions (ADRs) with frequency (uncommon). The Package Leaflet is updated accordingly. In addition, the MAH took the opportunity to introduce minor editorial changes to the PI. C.I.4 - Change(s) in the SPC, Labelling or PL due to new quality, preclinical, clinical or pharmacovigilance data	04/05/2023	06/06/2024	SmPC and PL	The Product Information is updated to add cholelithiasis and cholecystitis to the list of adverse drug reactions (ADRs) with frequency uncommon. For more information, please refer to the Summary of Product Characteristics.
IA/0032/G	This was an application for a group of variations. B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.a.1.f - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS -	03/03/2023	n/a		

	Changes to quality control testing arrangements for the AS -replacement or addition of a site where batch control/testing takes place				
T/0028	Transfer of Marketing Authorisation	16/11/2022	09/12/2022	SmPC, Labelling and PL	
IA/0029/G	This was an application for a group of variations. B.I.b.2.c - Change in test procedure for AS or starting material/reagent/intermediate - Other changes to a test procedure for a reagent, which does not have a significant effect on the overall quality of the AS B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	01/12/2022	n/a		
PSUSA/10577	Periodic Safety Update EU Single assessment -	23/06/2022	22/08/2022	SmPC and PL	Please refer to Suliqua EPAR:

/202111	insulin glargine / lixisenatide				Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation
IA/0027	A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient	10/03/2022	n/a		
II/0024	Submission of the final Clinical Study Report of the Category 3 PASS INSLIC08571, a 'Survey to evaluate the knowledge and understanding of the key safety messages in the healthcare professional guide and the patient guide'. The provision of the final survey results addresses post-authorisation measure (PAM) MEA 002.7. The updated RMP version 6.1 was agreed during the procedure. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	13/01/2022	n/a		n/a
IB/0025	B.II.f.1.b.5 - Stability of FP - Extension of the shelf life of the finished product - Biological/immunological medicinal product in accordance with an approved stability protocol	06/01/2022	22/08/2022	SmPC and PL	
R/0022	Renewal of the marketing authorisation.	16/09/2021	22/11/2021	SmPC, Annex II, Labelling and PL	
II/0023	Submission of the final study report from the "Patient registry of lixisenatide use in adult type 2 diabetes",	02/09/2021	n/a		n/a

	which is included as a Category 3 PASS in the RMP. This study's objective is to monitor the occurrences of events of interest including acute pancreatitis, pancreatic cancer and thyroid cancer, especially medullary carcinoma of the thyroid (MCT), among adult type 2 diabetes patients treated with Lixisenatide using the data from national registers and databases in Italy and Belgium. The provision of the study report addresses post-authorisation measure (PAM) MEA 005.3. C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority				
PSUSA/10577 /202011	Periodic Safety Update EU Single assessment - insulin glargine / lixisenatide	10/06/2021	n/a		PRAC Recommendation - maintenance
PSUSA/10577 /202005	Periodic Safety Update EU Single assessment - insulin glargine / lixisenatide	14/01/2021	n/a		PRAC Recommendation - maintenance
N/0020	Minor change in labelling or package leaflet not connected with the SPC (Art. 61.3 Notification)	05/11/2020	12/11/2021	PL	
IB/0017/G	This was an application for a group of variations. B.I.a.1.z - Change in the manufacturer of AS or of a starting material/reagent/intermediate for AS - Other variation B.I.c.1.z - Change in immediate packaging of the AS - Other variation	23/09/2020	n/a		

IG/1282	B.II.b.1.a - Replacement or addition of a manufacturing site for the FP - Secondary packaging site	15/09/2020	n/a		
IA/0018/G	This was an application for a group of variations. A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient B.I.b.2.a - Change in test procedure for AS or starting material/reagent/intermediate - Minor changes to an approved test procedure	03/09/2020	n/a		
IAIN/0015	C.I.z - Changes (Safety/Efficacy) of Human and Veterinary Medicinal Products - Other variation	10/08/2020	12/11/2021	SmPC, Annex II and PL	
PSUSA/10577 /201911	Periodic Safety Update EU Single assessment - insulin glargine / lixisenatide	11/06/2020	n/a		PRAC Recommendation - maintenance
WS/1819/G	This was an application for a group of variations following a worksharing procedure according to Article 20 of Commission Regulation (EC) No 1234/2008. B.I.a.2.c - Changes in the manufacturing process of the AS - The change refers to a [-] substance in the manufacture of a biological/immunological substance which may have a significant impact on the medicinal product and is not related to a protocol B.I.a.2.z - Changes in the manufacturing process of	05/06/2020	n/a		

	the AS - Other variation B.I.a.2.z - Changes in the manufacturing process of the AS - Other variation B.I.a.3.a - Change in batch size (including batch size ranges) of AS or intermediate - Up to 10-fold increase compared to the originally approved batch size B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation				
II/0011	Extension of Indication to include "treatment of adults with insufficiently controlled type 2 diabetes mellitus to improve glycaemic control as an adjunct to diet and exercise in addition to metformin with or without SGLT-2 inhibitors" based on the phase 3 Study EFC13794; a 26-week randomized, open-label, active controlled, parallel-group, study assessing the efficacy and safety of the insulin glargine/lixisenatide fixed ratio combination in adults with Type 2 Diabetes inadequately controlled on GLP-1 receptor agonist and metformin (alone or with pioglitazone and/or SGLT2 inhibitors), followed by a fixed ratio combination single-arm 26-week extension period. As a consequence, sections 4.1, 4.2, 4.4, 4.8 and 5.1 of the SmPC are updated and the Package Leaflet is updated in accordance. In addition, the MAH took the opportunity to update the contact details of the local representatives in Denmark, the Netherlands and Malta in the Package Leaflet and to implement minor editorial changes in the annexes. An updated RMP	30/01/2020	09/03/2020	SmPC, Annex II, Labelling and PL	Please refer to Scientific Discussion 'Suliqua-H-C-4243-II-0011'

	version 4.1 was agreed during the procedure. C.I.6.a - Change(s) to therapeutic indication(s) - Addition of a new therapeutic indication or modification of an approved one				
PSUSA/10577 /201905	Periodic Safety Update EU Single assessment - insulin glargine / lixisenatide	12/12/2019	17/02/2020	SmPC and PL	Refer to Scientific conclusions and grounds recommending the variation to terms of the Marketing Authorisation(s)' for PSUSA/10577/201905.
PSUSA/10577 /201811	Periodic Safety Update EU Single assessment - insulin glargine / lixisenatide	14/06/2019	n/a		PRAC Recommendation - maintenance
PSUSA/10577 /201805	Periodic Safety Update EU Single assessment - insulin glargine / lixisenatide	29/11/2018	n/a		PRAC Recommendation - maintenance
IG/0999/G	This was an application for a group of variations. A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or	20/11/2018	n/a		

	manufacturer of a novel excipient A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient A.4 - Administrative change - Change in the name and/or address of a manufacturer or an ASMF holder or supplier of the AS, starting material, reagent or intermediate used in the manufacture of the AS or manufacturer of a novel excipient				
IB/0007/G	This was an application for a group of variations. B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes B.II.e.5.a.2 - Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change outside the range of the currently approved pack sizes	13/09/2018	03/09/2019	SmPC, Labelling and PL	

PSUSA/10577 /201801	Periodic Safety Update EU Single assessment - insulin glargine / lixisenatide	06/09/2018	n/a		PRAC Recommendation - maintenance
PSUSA/10577 /201707	Periodic Safety Update EU Single assessment - insulin glargine / lixisenatide	08/02/2018	n/a		PRAC Recommendation - maintenance
IB/0005/G	This was an application for a group of variations. A.7 - Administrative change - Deletion of manufacturing sites B.I.a.4.z - Change to in-process tests or limits applied during the manufacture of the AS - Other variation	15/11/2017	n/a		
II/0003/G	This was an application for a group of variations. B.II.f.1.b.2 - Stability of FP - Extension of the shelf life of the finished product - After first opening (supported by real time data) B.II.f.1.c - Stability of FP - Change in storage conditions for biological medicinal products, when the stability studies have not been performed in accordance with an approved stability protocol	14/09/2017	19/04/2018	SmPC, Labelling and PL	
II/0002	C.I.13 - Other variations not specifically covered elsewhere in this Annex which involve the submission of studies to the competent authority	09/06/2017	n/a		
IAIN/0001	B.II.e.6.a - Change in any part of the (primary) packaging material not in contact with the finished product formulation - Change that affects the	30/03/2017	19/04/2018	SmPC, Labelling and	

	product information			PL	